UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/041,975	03/13/1998	MARC ALIZON	2356.0011-06	4167

22852 7590 12/29/2004

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/041,975	ALIZON ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,25-41 and 43-47* is/are pending in the application.

4a) Of the above claim(s) *26-41 and 47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23, 25, 43-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Office Action

37 C.F.R. § 1.114

A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed 15 October, 2004, in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicants' submission filed on 16 August, 2004, has been entered.

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 16 August, 2004. Claims 23, 25-41, and 43-47 are pending in the instant application. Claims 26-41 and 47 stand withdrawn from further consideration by the Examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. Claims 23, 25, and 43-46 are currently under examination. Applicants are reminded that pursuant to M.P.E.P. § 818.02(a) where claims to another invention are properly added and entered in the application before an action is given, they are treated as original claims for purposes of restriction only. The claims originally presented and acted upon by the Office on their merits determine the invention elected by an applicant in the application, and in any request for continued examination (RCE) which has been filed for the application. **Subsequently presented claims to an invention other than that acted upon should be treated as provided in M.P.E.P. § 821.03.** Accordingly, newly submitted claim 47 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: newly presented claim 47 is directed toward a viral variant with a

different genotypic and phenotypic properties from the virus currently under examination. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 47 is withdrawn from further consideration as being directed towards a nonelected invention (refer to 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03).

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23, 25 and 43-46 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Rochester*, 358 F.3d 916, 69 U.S.P.Q.2d 1886 (C.A.F.C. 2004). As previously set forth, the claimed invention is broadly directed toward purified HIV-1 variants that differ genetically in the *gag*, *pol*, and *env* coding regions from three known HIV-1 prototypes (e.g., IIIB, BRU, and ARV-2) by the specified amounts (e.g., 3.4% in Gag, 3.1% in Pol, and 13.0% in Env). Additional limitations simply specify that patient antisera are capable of recognizing the variant Gag, Pol, and Env proteins, as well as, the Gag, Pol, and Env proteins of HIV-1_{MAL}. Another

limitation simply specifies that the variants contain the common genomic structural organization of HIV (e.g., 5'-LTR-gag-pol-vif-vpr-tat-rev-vpu-env-LTR-3'). Finally, the most recent limitation specifies that the nucleic acid of said variant can be detected by stringent hybridization conditions. Accordingly, the claim language encompasses a large genus of genotypically/phenotypically distinct human immunodeficiency viruses.

Applicants are reminded that the essence of the statutory requirement governing written description is whether one skilled in the art, familiar with the practice of the art at the time of the filing date, could reasonably have found the later claimed invention in the specification as filed. *In re Kaslow*, 707 F.2d 1366, 1375, 217 U.S.P.Q. 1089, 1096 (Fed. Cir. 1983). *In re Wilder*, 736 F.2d 1516, 1520 222 U.S.P.Q. 349, 372 (Fed. Cir. 1984, *cert. denied*, 469 U.S. 1209 (1985). *Texas Instruments, Inc.* v. *International Trade Comm'n*, 871 F.2d 1054, 1063, 10 U.S.P.Q.2d 1257, 1263 (Fed. Cir. 1989). Moreover, the courts have stated that the evaluation of written description is highly fact-specific, and that broadly articulated rules are inappropriate. *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976). *In re Driscoll*, 562 F.2d 1245, 1250, 195 U.S.P.Q. 434, 438 (C.C.P.A. 1977). It is also important to remember that the true issue in question is not whether the specification enables one of ordinary skill in the art to make the later claimed invention, but whether or not the disclosure is sufficiently clear that those skilled in the art will conclude that the applicant made the invention having the specific claim limitations. *Martin* v. *Mayer*, 823 F2d 500, 505, 3 U.S.P.Q.2d 1333, 1337 (Fed. Cir. 1987).

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor has possession of the claimed invention. See, e.g., *Vas-*

Cath, Inc. v. *Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood* v. *American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. *Fujikawa* v. *Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1996).

As previously set forth, and contrary to applicants' assertions, the disclosure only describes the molecular cloning and characterization of a single novel HIV-1 isolate, designated LAV-1_{MAL}. For example, the specification clearly states (bridging paragraph, pp. 2 and 3) that "**a new virus** has been discovered that is responsible for diseases clinically related to AIDS and that can be classified as a LAV-1 virus but that differs genetically from known LAV-1 viruses to a much larger extent than the known LAV-1 viruses differ from each other. **The new virus is basically characterized by the cDNA sequence which is shown in Figures 7A to 7I**, and this new virus is hereinafter generally referred to as

"**LAV_{MAL}**." The disclosure provides a restriction map for a molecular clone of HIV-1_{MAL} (see CHARACTERIZATION AND MOLECULE CLONING OF AN AFRICAN ISOLATE, pp. 7 and 8, and Figure 1). The **complete nucleotide sequence** and **deduced amino acid sequence** of this **clone** were ascertained (see Figure 7). The nucleotide sequence and deduced amino acid sequence of this novel isolate were compared to other known HIV-1 isolates (e.g., BRU, ELI, and ARV-2) (see Figures 1B-4 and 6). Based upon this comparison the inventors made three general conclusions. First, it was noted (specification, p. 10) that "the protein sequences of the LAV_{ELI} and LAV_{MAL} are more divergent from LAV_{BRU} that are those of HTLV-3 and ARV-2 (FIG. 4A)". Second, applicants reported that the *env* gene is more variable than the *gag* and *pol* genes. Third, it was reported that the divergence between LAV_{ELI} and LAV_{MAL} was comparable to that between LAV_{BRU} and each of the isolates. Thus, **the skilled artisan would reasonably conclude that applicants have identified, cloned, and characterized a novel HIV-1 isolate designated MAL. The skilled artisan would also reasonably conclude that applicants ascertained the genetic relatedness of this particular isolate to other known HIV-1 isolates such as HIV-1 ELI, BRU, and ARV-2.** However, the skilled artisan would **not** reasonably conclude that applicants were in possession of any other HIV-1 variant, particularly one with the claimed limitations. **The disclosure fails to provide any other molecular clones and their attendant nucleotide/amino acid sequences. The disclosure fails to identify the isolation, characterization, and nucleotide sequence of other variant HIV-1 MAL isolates.** Thus, the applicants were clearly **not** in possession of the claimed subject matter at the time of filing and the claim language clearly represents an unwarranted attempt to capture subject matter that was clearly not invented by the applicants.

Applicants now argue that the facts in this application are analogous to Enzo, wherein deposited microorganisms were sufficient to support more generic claim language. This argument is not convincing since the fact pattern is actually quite different in this application. The claims of the instant application are directed to HIV-1 variants having specific genetic variations. In particular, the claimed variants must display at least 3.4%, 3.1%, and 13.0% genetic variation in the *gag*, *pol*, and *env* coding regions. Thus, the claims encompass a large and poorly defined group of disparate genotypic and phenotypic isolates. It may encompass intrapatient variants, interpatient variants, and viruses from different clades. Moreover, because of the overall genetic relatedness of these viruses, simply specifying that the nucleic acid can be detected by a probe that hybridizes to the parent MAL isolate is insufficient. These viruses are approximately 9.5 kb in length. Some regions are quite conserved whereas other regions are quite diverse. Simply performing a hybridization experiment will need provide any detailed structural information. It will not tell the skilled artisan if the degree of genetic relatedness meets the claimed limitations. Once again, it must be emphasized that nothing in the disclosure leads the skilled artisan to any particular variant with the claimed structure. Accordingly the rejectionis proper and maintained.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 23, 25 and 43-46 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Myers *et al.* (1990). Applicants' again contend that the claims are fully supported by the disclosure and are entitled to the benefit of priority to earlier filed U.S. and French applications. As previously set forth, and contrary to applicants' assertion, this application clearly fails to provide an adequate

written description of the claimed invention and priority cannot be extended under 35 U.S.C. § 119 or 120. Accordingly, the following art rejection is proper and hereby maintained. Myers *et al.* (1990) provide the complete nucleotide sequence of a novel purified HIV-1 isolate designated Z2Z6. This isolate is genetically related to the HIV-1 isolates ELI and MAL and appears to be only distantly related to the isolates BRU, IIIB (or HXB2), and ARV-2 (SF-2). Nucleotide sequence and amino acid analysis demonstrated that this isolate appears to vary from the aforementioned prototypical isolates BRU, IIIB, and ARV-2 by at least 3.4%, 3.1%, and 13.0% in the *gag*, *pol*, and *env* coding regions, respectively. Thus, this isolate appears to meet all the limitations of the claimed invention. Moreover, because of the close genetic relatedness between Z2Z6 and the isolates ELI and MAL, one of ordinary skill in the art would reasonably expect nucleic acid probes and antibodies, specific for MAL to also recognize Z2Z6 nucleic acids and antigens.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through

Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

26 December, 2004